REMARKS

Claims 1 - 42 and 47 - 60 have been withdrawn from consideration. Claims 43 - 46 and 61 remain pending in this application. In view of the following remarks, it is respectfully submitted that all of the presently pending claims are allowable.

Claims 43, 44 and 61 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yoon (U.S. Patent No. 5,797,888).

Claim 43 recites a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter*."

In contrast, Yoon purports to show a cannula for insertion through an anatomical cavity wall. (See Yoon, Abstract). The cannula 20 has a tubular body 22 with a valve 26 at a proximal end thereof which is designed to open only when a trocar 36 is thrust therethrough. (See id., col. 4, lines 18-20). The valve 26 includes four flaps (valve members) 28-34 biased toward a closed position "when no instrument is passed through the cannula." (See id., col. 4, lines 1-3). The flaps 28-34 open outwardly only when the trocar 36 is pushed therethrough. (See id., col. 4, lines 27-32). The valve of Yoon is useful only to prevent fluid from passing therethrough as it seals around the trocar 36 when such is passed therethrough and seals tight when no instrument extends therethrough.

The Examiner stated that the slit in Yoon is configured to open inwardly when the ambient pressure exceeds the lumen pressure. (See 3/24/06 Office Action, ¶ 5). However, that reading of Yoon is directly contradictory to the teachings contained therein. Specifically, Yoon describes the valve 26 as a one way valve configured "such that external forces and pressures exerted on the valves from the outside the cannula will not cause the valves to open [into the cannula 20]." (See Yoon, col. 7, lines 59-62). "Furthermore, spring members, like spring

members 84, can be embedded in any of the valves and in any orientation relative to a longitudinal axis of the cannula to provide reinforcement and to bias the valves to a closed condition." (See id., col. 8, lines 2-6).

Accordingly, the device of Yoon teaches away from the configuration claimed by the applicants. The applicants have disclosed a catheter that opens in response to a difference between a fluid pressure in the lumen and a fluid pressure external to the catheter. To accomplish the aspiration function, the compound slit is "able to flex into the internal lumen" when the lumen pressure is less than the environmental pressure. The valve 26 in Yoon never opens inwardly and only opens outwardly as a result of being physically pushed by the trocar 36. The valve 26 acts to prevent all fluid flow back into the cannula 20.

Thus, it is respectfully submitted that Yoon neither illustrates nor describes a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter*," as recited in claim 43. It is therefore respectfully submitted that claim 43 is not anticipated by Yoon and that this rejection should be withdrawn. Because claims 44 and 61 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable.

Claims 43, 44 and 61 stand rejected under 35 U.S.C. § 102(b) as anticipated by Eaton (U.S. Patent No. 3,303,847). The Examiner stated, in support of the rejection, that the slit in Eaton is configured to open inwardly when the ambient pressure exceeds the lumen pressure. (See 3/24/06 Office Action, ¶ 6).

It is respectfully submitted that Eaton fails to show a compound slit "biased toward a closed position and *opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter*," as recited in claim 43. Eaton shows a "collapsible or squeezable tube" which opens only when the body portion 1 is physically

deformed by a manual pressure applied thereto and which remains closed at all times when no manual pressure is applied. Specifically, Eaton states that "pressure applied to the body portion 1 will cause the slits or cuts 8 and 9 of the flexible catheter to part slightly. (Specification, col. 3, lines 67 - 68). Eaton further states that, "when the container is not subjected to pressure, such [an] opening will remain closed sufficiently tightly to retain the contents of the container-applicator against the force of gravity." Id., col. 3, line 73 - col. 4, line 1).

Accordingly, it is submitted that Eaton describes a valve which opens only under physically deforming, manual pressure and teaches away from a valve opening in response to fluid pressure as recited in claim 43.

Thus, it is respectfully submitted that Eaton neither illustrates nor describes a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter*," as recited in claim 43.

It is therefore respectfully submitted that claim 43 is not anticipated by Eaton and that this rejection should be withdrawn. Because claims 44 and 61 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable.

Claims 43, 44 and 61 stand rejected under 35 U.S.C. § 102(b) as anticipated by Ferguson (U.S. Patent No. 2,063,424).

Initially, it is respectfully submitted that Ferguson does not show a catheter as recited in claim 43. A catheter is a tubular device "designed for insertion into canals, vessels, passageways, or body cavities so as to permit injection or withdrawal of fluids or substances or to maintain the openness of a passageway." (Webster's Third International Dictionary, 1986). This definition is entirely consistent with the detailed description and figures of the present invention. In contrast, the nipple for a baby's bottle shown by Ferguson is designed to be grasped between a baby's lips and is not suitable for the injection to or withdrawal of any substance from a body

cavity. Injection is defined as driving or forcing fluid into a vessel, cavity or tissue (Id.) while the nipple is simply a container from which the baby draws fluid under suction. In addition, it is submitted that, similar to Eaton, the valve of Ferguson does not open in response to fluid pressure applied thereto. Rather, the valve of Ferguson is opened by the physical deformation of the nipple as it is squeezed in the mouth of the infant with the suction drawing the liquid through this opening. Specifically, Ferguson states that, during use:

> the nipple is of course positioned between the jaws of infant; and obviously, closure of the infant's jaws will compress the nipple from above and below, with the result that the slots will gape in the manner illustrated in Figs. 4 and 5...It will be readily understood, that when the nipple is applied to a bottle containing liquid food; the normal jaw action of the infant in the act of nursing will regulate the size of the orifice and consequently the flow of food.

Specification, page 1, col. 2, line 49 to page 2, col. 1, line 17).

Thus, it is submitted that the nipple is designed to open only when compressed between the jaws of an infant and not due to a pressure differential. That is, the pressure differential due to the infant's sucking may enlarge an opening caused by the compression in the jaws, but does not open the nipple on its own. (Id., page 2, col. 1, lines 20 - 23). The Examiner stated that the slit of Ferguson is biased closed and opens due to differences in pressure between the lumen and the ambient. (See 3/24/06 Office Action, ¶ 7). In addition, Ferguson states that the improved nipple contains a central perforation 6 and that "no amount of either compression or distortion can possibly close this vent 6.". (Id., page 2, col. 2, lines 18-22; Fig. 7). Furthermore, the intersecting slots 3, 4, and 5 are never fully closed and "no amount of compression or distortion can possible close the slots 3, 4, 5." (Id., page 2, col. 2, lines 63 - 65).

Thus, it is respectfully submitted that Ferguson neither illustrates nor describes a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter*,"

as recited in claim 43. It is therefore respectfully submitted that claim 43 is not anticipated by Eaton and that this rejection should be withdrawn. Because claims 44, 46, and 61 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable.

Claims 43, 44 and 46 stand rejected under 35 U.S.C. § 102(b) as anticipated by Yamauchi (U.S. Patent No. 3,718,140).

Similarly to Ferguson, Yamanuchi shows a nipple for a baby bottle which is designed to open through the jaw action of an infant. Yamanuchi describes the nipple as allowing the infant to suck the milk in an amount in proportion to the sucking force. (Specification, col. 3, lines 25 - 27). However, it is clear that this bottle does not require an infant to learn some new method of sucking and that this description refers to the natural process whereby the nipple is compressed between the jaws of the infant and physically deformed to initiate the flow of milk. Accordingly, it is respectfully submitted that similarly to the nipple of Ferguson, Yamuchi fails to show or suggest a medical device comprising "an elongate catheter including an external surface and at least one internal surface defining an internal lumen that extends longitudinally along at least a portion of the elongate catheter" and "a compound slit extending from a generally hemispherical portion of the external surface to the at least one internal surface and into communication with the internal lumen, *the compound slit being biased toward a closed position and opening in response to a difference between a fluid pressure within the lumen and a fluid pressure outside the catheter*," as recited in claim 43. It is therefore respectfully submitted that claim 43 is not anticipated by Eaton and that this rejection should be withdrawn. Because claims 44 and 46 depend from and, therefore, include all of the limitations of claim 43, it is respectfully submitted that these claims are also allowable.

Claim 45 stands rejected as obvious over Eaton in view of Engelson et al. (U.S. Patent No. 5,798,018) and stands rejected as obvious over Yoon in view of Engelson et al. (U.S. Patent No. 5,798,018). However, Engelson does not cure the deficiencies described above with reference to Eaton and Yoon. Claim 45 depends from and therefore, includes all the limitations of claim 43. Thus, it is respectfully submitted that claim 45 is allowable for the same reasons stated above in regard to claim 43.

It is therefore respectfully submitted that all of the presently pending claims are allowable. All issues raised by the Examiner having been addressed, an early and favorable action on the merits is earnestly solicited.

Respectfully submitted,

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